

REMARKS

I. Claim Amendments

By the foregoing amendments to the claims, claim 52 has been amended, claims 1-14, 18, 19, 24-49, and 51 have been canceled, and new claims 58-62 have been added.

In particular, claim 52 has been amended to more precisely define the first and second resin members and to clarify the claimed method. Support for these amendments can be found at least at paragraphs 109-114 and at Example 3 (paragraphs 146-150) of the present specification as filed. In addition, the phrase "by covalent bonding directly to a resin member without passing through protein" is supported at least at paragraph 48 of the specification, which shows that cycloolefin substrate activated by aldehyde treatment and the nucleic acid react as follows: COP(cycloolefin polymer)- CHO + NH₂ - nucleic acid COP - CH = nucleic acid + H₂O. That is, through the formation of the Schiff base and dehydration reaction, a covalent bond is formed.

The new claims are supported at least at paragraphs 109-114 of the specification.

The amendments to the claims, including cancellation of claims, have been made without prejudice or disclaimer to any subject matter recited or canceled herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments to the claims is respectfully requested.

II. Response to Claim Rejections Under 35 U.S.C. § 112

A. Claims 1-14, 18, 19, 24-49, 51 and 52 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

In particular, the Examiner has stated that the meaning of the phrases "arbitrary base sequence," "immunological substances" and "receptor binding substances" are not clear.

Applicants note that the claims as amended do not include the phrases at issue. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

B. Claim 52 has been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement.

In particular, the Examiner has stated that the application does not support the broad limitation "resin," only certain resin species.

Not to acquiesce to the rejection, but to advance prosecution, claim 52 has been amended herein to recite that the resin is selected from certain resin species. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

III. Response to Claim Rejections Under 35 U.S.C. § 103

Claims 1-14, 18, 19, 24-49, 51 and 52 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hu (U.S. Publication No. 2002/0048823, in view of Li (U.S. Publication No. 2004/0018495 and Wilding et al. (U.S. Patent No. 5,637,469). This rejection is respectfully traversed.

Applicants respectfully submit that the cited references, taken alone or in combination, do not teach or suggest the subject matter of the present claims.

Example 3 of the present application describes an embodiment wherein an analytical device is produced by using the first member and the second member which both comprise a resin. Example 3 also demonstrates that Hbs can be detected by using an analytical device which had been prepared by immobilizing an oligonucleotide to the member by direct covalent bond without passing through protein and hereafter conducting the thermal fusion of the first member and the second member.

An antibody which has lower a thermal resistance than that of oligonucleotides (for example, the anti-Hbs antibody in Example 3) is immobilized on the capture zone after the thermal fusion by introducing in the form of the reagent A into the passage. That is, in the case of the microchip of the present invention, an antibody which has lower thermal resistance than that of oligonucleotides is not present in the passage during the thermal fusion. Consequently, the analytical device of the present invention can evade thermal influence by the thermal fusion to antibody.

In the analytical device of the present invention, the nucleic acid is immobilized to the member before thermal fusion directly in a microchannel by covalent bond. According to the present invention, it does not make, for example, a protein such as the BSA as the spacer interposed between the nucleic acid and the member in order to immobilize the nucleic acid to the member. In the method used for producing the microchip of the present invention, the nucleic acid can be directly bonded to the member by covalent bonding without passing through

a protein, and the bonding is very firm. If in contrast to the present method the bonding of the nucleic acid to the member is hydrophobic bonding such as bonding by making proteins intervene, which is inferior in the bonding strength compared to the covalent bonding, the bonded nucleic acid easily comes loose and falls when the product is exposed to a high temperature by thermal fusion. Also, when protein is used as a spacer, and the nucleic acid is immobilized to the member by passing through the protein, proteinaceous degeneration is caused by heat in the thermal fusion, and nonspecific reaction may become higher in the protein that nonspecific reaction is very usually low.

The present invention does not have these inconveniences. Therefore the present invention realizes a reliable analytical device.

In contrast to the present claims, Wilding et al. teaches that "The inside surface of the channels were coated with anti-A (1:10 dilution) by first filling the channel with the antibody (capillary action) and allowing it to dry" (Example 1 of the reference). This description does not indicate that the nucleic acid is immobilized to the member directly in the microchannel by covalent bond before thermal fusion like the analytical device of the present invention. Since the bond of the antibody in Wilding et al. depends on coating, so that bonding power is weaker than a covalent bond, the antibody easily comes loose and falls.

Hu merely shows that an avidin which binds covalently with an antibody conjugates with the base substrate which is coated with a biotin, by biotin-avidin conjugation. Hu does not teach or suggest that the nucleic acid is immobilized to the member directly in the microchannel by direct covalent bonding without passing through protein before thermal fusion like the analytical device of the present invention.

Li merely represents devices and analytical methods using an antibody detection chemical reagent (containing an oligonucleotide linker) which binds to a solid substrate. However, Li does not teach or suggest that the nucleic acid is immobilized to the member directly in the microchannel by direct covalent bonding without passing through protein before thermal fusion like analytical device of the present invention.

In summary, the cited references do not teach or suggest nucleic acid fixed to a member by direct covalent bonding without passing through a protein before thermal fusion. In addition, the cited references do not teach or suggest a process whereby antibody is fixed after thermal

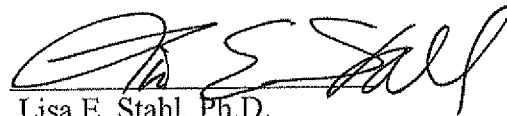
fusion in the capture zone. For at least these reasons, the references do not teach or suggest the method to produce a reliable analytical device as recited in the present claims. In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

CONCLUSION

In view of the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order. Such action is earnestly solicited.

In the event that there are any questions related to this response, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney at the below-listed telephone number concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

By: 
Lisa E. Stahl, Ph.D.
Registration No. 56,704

BACON & THOMAS PLLC
625 Slaters Lane, Fourth Floor
Alexandria, Virginia 22314-1176
703.683.0500

Date: January 25, 2011